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Using The Endangered Species Act to Preempt Constitutional Challenges to GMO Regulation

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Introduction

Scientific studies show that genetically modified organisms ("GMOs") have an adverse impact on biodiversity, especially pollinating species. Enforcement of the laws regulating the introduction of GMOs into the environment has not kept pace with this finding. A Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) of three federal agencies—the United States Department of Agriculture ("USDA"), the Environmental Protection Agency ("EPA"), and the Food and Drug Administration ("FDA")—regulates biotechnology in the marketplace and the environment.[1] Under existing judicial interpretation of the Coordinated Framework, a loophole exists. With this loophole, none of these agencies are responsible for assessing the cumulative environmental impacts of GMOs on the biodiversity of endangered or threatened species. An analysis of GMO regulation under the Endangered Species Act of 1973 ("ESA") suggests that this statute provides the best means to close this loophole.

Under the ESA, the Fish and Wildlife Service ("FSW") must assess and issue an opinion about the biological impacts of proposed governmental action whenever that government action might endanger the continued survival of an endangered species.[2] This Note

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1. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

2. Endangered Species Act of 1973, 16 U.S.C. § 1536 (2012) (also referred to as "§ 7 consultation").

posits that, since GMO deregulation impacts endangered pollinators, the ESA mandates that the FWS evaluate the impact of GMOs on the biodiversity of endangered pollinators. Since protection of these and certain other endangered or threatened species improves agriculture, which clearly affects interstate commerce, ESA's mandatory consultation provision is a constitutional exercise of Congress' power under the Commerce Clause. Thus, the regulation of GMOs under the ESA is preferable to state and local attempts to regulate labeling or ban GMOs. This is because this state action arguably impacts interstate commerce by discriminating against the free flow of products into the state. Unlike state and local efforts to regulate labeling or banning of GMOs, the ESA's mandatory § 7 consultation provision is not subject to constitutional Commerce Clause challenges. Furthermore, due to the adverse impact that GMOs have on endangered species, state and local deregulation of GMOs directly conflicts with the purpose and enforcement of the ESA, and thus the ESA preempts such deregulation.

This Note consists of seven sections aimed at showing the shortcomings of GMO regulation with respect to protecting endangered pollinators. This Note also shows how the ESA requires evaluation of the biodiversity impacts from GMOs for the overall effectiveness of the ESA's regulatory scheme. Section I discusses what GMOs are and their prevalence in agriculture. Section II explains the current Coordinated Framework approach to deregulation of GMOs and how the existing GMO regulatory framework fails to protect biodiversity. Section III addresses the impacts of GMOs on endangered pollinators. Section IV presents the scientific evidence showing that GMOs threaten the continued survival of endangered pollinating species. Section V examines the only Supreme Court decision, *Monsanto Co. v. Geertson Seed Farms*,[3] reviewing deregulation of GMOs for their impacts on the environment and biodiversity. Section VI discusses the ESA as preempting state law (and therefore avoiding dormant Commerce Clause issues) under the Supremacy Clause. Section VII discusses ESA regulation under both the Commerce Clause and Necessary and Proper Clause.

3. Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139 (2010).

I. Overview of GMOs

In 2011, the Food and Agricultural Organization ("FAO") of the United Nations ("UN") found that seventy-five percent "of the Earth's plant genetic diversity has been lost since 1900 as farmers shift to genetically uniform, mass-produced crop varieties."[4] The World Health Organization defines genetically modified organisms ("GMOs") as "organisms (i.e., plants, animals or microorganisms) in which the genetic material ("DNA") has been altered in a way that does not occur naturally by mating and/or natural recombination."[5] Dubbed "modern biotechnology," "genetic engineering" ("GE"), or "GM foods,"[6] the process "allows selected individual genes to be transferred from one organism into another, also between non-related species."[7]

Regulatory agencies do not consider the means of production in assessing crop differences; rather, agencies consider GMOs the substantial equivalent of their natural counterparts, due to their similar phenotypic expression.[8] Thus, the Coordinated Framework advocates that genetic modification is innocuous: If it looks like an apple and tastes like an apple, then it is an apple.[9] Since 1996, herbicide-tolerant and insecticide-resistant GMO strains have been the only types of GMOs on the market in the United States.[10] *Bacillus Thuringiensis* (Bt) crops contain DNA from the Bt bacterium, which codes for proteins that kill insects that ingest Bt

4. Deniza Gertsberg, *Loss of Biodiversity and Genetically Modified Crops*, GMO J. (June 17, 2011), http://gmo-journal.com/2011/06/17/loss-of-biodiversity-and-genetically-modified-crops/.

5. *20 Questions on Genetically Modified Foods*, WORLD HEALTH ORG. (2002), http://www.who.int.foodsafety/publications/biotech/20 questions/en/index.html

6. *Id.*

7. *Id.*

8. Phenotypic expression is the physical, genetic expression of an organism; whereas a genotype describes the actual genetic makeup of an organism, whether or not a particular gene is physically expressed in that organism.

9. Stephen Tan & Brian Epley, *Much Ado About Something: The First Amendment and Mandatory Labeling of Genetically Engineered Foods*, 89 WASH. L. REV. 301, 306 (2014).

10. JORGE FERNANDEZ-CORNEJO ET AL., U.S. DEP'T OF AGRIC., GENETICALLY ENGINEERED CROPS IN THE UNITED STATES,. 5–6, (Feb. 2014) (The USDA has approved field releases of other kinds of GE crops for testing, such as drought resistant varieties, but these have not gained market approval.), http://www.ers.usda.gov/media/1282246/err162.pdf.

crops' plant tissue.[11] Herbicide-tolerant GMOs enable farmers to spray herbicides to eliminate weeds, without affecting the genetically modified (GM) crop.[12]

Crops created from biotechnology cover 100 times more surface area than when they were first planted in 1996: from 1.7 million hectares to over 175 million hectares.[13] Almost half of the world's soybeans and a third of its corn are biotech produced.[14] The United States leads the world in GM crop production.[15] Industry developers of GMOs assert that GMOs protect the environment because they include a component that is either tolerant to herbicides or produces pesticidal compounds, thereby reducing the use of pesticides and herbicides in agriculture.[16] However, since the introduction of GM crops in 1996, pesticide use increased by an estimated 404 million pounds or by about seven percent.[17] Studies show that the introduction of GMOs into the agricultural system actually increases the use of toxic chemicals and negatively impacts the biodiversity of nontarget organisms, including those listed as endangered or threatened to be endangered.[18]

II. The Coordinated Framework Approach to Deregulation of GMOs

The Coordinated Framework views genetically engineered organisms as the substantial equivalent of organisms produced by natural processes. This approach to regulation, known as the

11. Jong Yul Roh et al., Bacillus thuringiensis *as a Specific, Safe, and Effective Tool for Insect Pest Control*, 17 J. MICROBIOLOGY BIOTECH. 547, 553–54 (2007).

12. *Herbicide Resistant Crops*, GMO Compass (Dec. 11, 2006), http://www.gmo-compass.org/eng/agri_biotechnology/breeding_aims/146.herbicide_resistant_crops.html.

13. Clive James, *Global Status of Commercialized Biotech/GM Crops: 2013*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH 1, 1 (2013), http://www.isaaa.org/resources/publications/briefs/46/executivesummary/pdf/Brief%2046%20-%20Executive%20Summary%20-%20English.pdf.

14. Michael Specter, *Seeds of Doubt: An Activist's Controversial Crusade Against Genetically Modified Crops*, THE NEW YORKER, Aug. 25, 2014, at 46.

15. James, *supra* note 13, at 3.

16. WORLD HEALTH ORG., *supra* note 5.

17. Charles M. Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the U.S.*, ENVIRONMENTAL SCIENCES EUROPE 1, 3 (2012), http://www.enveurope.com/content/pdf/2190-4715-24-24.pdf.

18. See Lora A. Morandin & Mark L. Winston, *Wild Bee Abundance and Seed Production in Conventional, Organic, and Genetically Modified Canola*, 15 ECOL. APPLICATIONS 871, 876–77 (2005) for a more in depth discussion of the correlation between wild bee populations and pollination deficits in GM agricultural plots as compared to conventional and organic plots.

substantial equivalence principle, enables the Coordinated Framework to regulate all organisms the same way, regardless of whether the process creating that organism was natural or through genetic engineering.[19] The substantial equivalence principle essentially is a "safe until proven otherwise" theory, which allows the "approval of new products that are substantially equivalent to natural ones in the absence of significant adverse effects on production and consumption."[20] The FDA may issue regulations to restrict market-release of GMOs if there is an adverse effect on human health from consumption.[21] The EPA only has jurisdiction over a GMO when that GMO contains pesticide-producing genetic material and must permit GMO introduction as long as the specific chemical compounds of the encoded pesticide do not adversely impact human health and the environment.[22] The USDA must deregulate a GMO in the absence of a plant-pest risk.[23] In determining the presence of adverse effects on production and consumption, agencies rely on the scientific evidence set forth by the applicant.[24] Once the GMO is approved for

19. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

20. Katherine Wilinska, Note, *AquAdvantage is Not Real Advantage: European Biotechnology Regulations and the United States' September 2010 FDA Review of Genetically Modified Salmon*, 21 MINN. J. INT'L L. 145, 152–53 (2012).

21. U.S. FOOD & DRUG ADMIN., *FDA's Role in Regulating Safety of GE Foods* 1, 3 (May 9, 2014), http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM352193.pdf.

22. 7 U.S.C. § 136a(c)(5)(C)–(D) (2014); U.S. ENVTL. PROT. AGENCY, *EPA's Regulation of Biotechnology for Use in Pest Management* (May 14, 2014), http://www.epa.gov/pesticides/biopesticides/reg_of_biotech/eparegofbiotech.htm.

23. 7 U.S.C. § 7712(a) (2012); Ctr. for Food Safety v. Vilsack, 844 F. Supp. 2d 1006, 1018 (N.D. Cal. 2012) (holding that USDA-APHIS interpretation of the Plant Protection Act was entitled to deference: namely, that in the absence of a plant-pest risk, APHIS does not have regulatory authority to continue managing GMOs); ANIMAL & PLANT HEALTH INSPECTION SERV., *Petitions*, U.S DEP'T OF AGRIC., https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_permits_notifications_and_petitions (follow "Petitions" hyperlink) (last modified Aug. 3, 2015).

24. U.S. FOOD & DRUG ADMIN., *Biotechnology: Genetically Engineered Plants for Food & Feed*, http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/default.htm (last updated May 6, 2015) (The FDA "require[s] developers submit a scientific and regulatory assessment of the bioengineered food 120 days before the bioengineered food is marketed" and the FDA "recommends that developers continue the practice of consulting with the agency.") (emphasis added); ANIMAL & PLANT HEALTH INSPECTION SERV., *Permits, Notifications, and Petitions*, U.S. DEP'T OF AGRIC., https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_permits_notifications_and_petitions (last modified Aug. 3, 2015) (APHIS-USDA deregulates GMOs "[w]hen a developer has collected enough evidence that a GE organism poses no more of a plant pest risk that an equivalent non-GE organism.") (emphasis added); U.S. LIBRARY OF CONG., *Restrictions*

deregulation, the regulatory agency ceases oversight of the introduced GMO.[25] This lack of oversight means there is no required review or measurement of the impact of the approved, i.e., deregulated, GMOs on biodiversity after deregulation.[26]

Though the USDA claims it works with the EPA to determine the environmental risks from a proposed new GMO, such as impacts on nontarget species,[27] both agencies operate under the assumption that "potential risks associated with [GM] organisms fall into the same general categories as those created by traditionally bred organisms."[28] This substantial equivalence approach is fundamentally at odds with effective regulation of biodiversity threats: where GMOs are assumed to pose the same risks as other crops, an agency does not have to look at the indirect effects on biodiversity unique to GMOs; where oversight completely ceases with the deregulation of GMOs, an agency does not have to look at the cumulative environmental effects over time.[29]

While the Coordinated Framework claims it regulates GMOs for their safety regarding health, the environment, and agriculture, all three agencies approve GMOs for deregulation based on information presented by the industry applicant and stop oversight cases once

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on Genetically Modified Organisms: United States, http://www.loc.gov/law/help/restrictions-on-gmos/usa.php (last updated June 9, 2015) (EPA requires that pesticides be registered before commercial distribution and "[p]esticides must be tested and shown to be safe before they can be registered." Therefore, "[a] registration application must include information regarding testing, identity of the product, draft labeling, information on tolerance of residues, and other safety-related information." Further, "if the producer of the [GMO] obtains information regarding adverse effects from the [GMO] on human health or the environment, it must share it with the EPA.") (emphasis added).

25. U.S. DEP'T OF AGRIC., *Biotechnology Frequently Asked Questions (FAQs)*, http://www.usda.gov/wps/portal/usda/usdahome?navid=AGRICULTURE&contentid=BiotechnologyFAQs.xml (last modified May 15, 2015) ("6. What are the roles of government in agricultural biotechnology?").

26. An approved GMO is the same as a deregulated GMO—agencies "approve" a GMO for "deregulation."

27. An impact on a "nontarget" organism means that, while the organism was not the intentional "target" of the product (GMO, pesticide, etc.), the organism was nonetheless affected by that product.

28. U.S. DEP'T OF AGRIC., *supra* note 25.

29. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986) (The process for deregulation of GMOs and for the approval of their subsequent release into the environment depends on the presence of pesticidal compounds. The EPA oversees the permitting process for these organisms along with APHIS; if the GMO does not produce pesticidal compounds, then APHIS regulates its release into the environment.).

they decide to deregulate.[30] The substantial equivalence doctrine, which is the foundation of the United States GMO regulatory system, is antithetical to the protections that the Coordinated Framework promises. If the priority is human and environmental safety, rather than the fastest method to introduce consumer goods on the market, the United States must take a fundamentally different approach to GMO regulation. Regulators should not give GMO manufacturers the benefit of the doubt when GMOs have uncertain and wide-reaching impacts.

III. Species Surveys and Policy Trends Support the Unfortunate Truth That Pollinating Species Are on the Brink of Extinction

The world is currently in the sixth mass extinction: we have already exceeded the number of extinctions that occurred in the previous five mass extinctions.[31] Normally, a thirty percent decline in the number of species occurs once every ten million years, but over forty percent of all species evaluated by the International Union for Conservation of Nature ("IUCN") are currently threatened with extinction.[32] This species decline is directly impacting agricultural outputs. The world is facing a "bee-pocalypse" where honey bees—nature's primary pollinators, which enable the production of at least ninety commercially grown crops in America—have been dying off en masse.[33] Pollinators assist over eighty percent of the world's flowering plants and contribute more than $24 billion to the U.S. economy—of which honey bees account for $15 billion and native insect pollination contributes $9 billion.[34] Fruit and seed production require animal pollination, primarily from bees, for one or more cultivars of seventy percent of the world's 1300 crops.[35] A combination of stressors contribute to the bee disappearance and pollinator-extinction more generally, including loss of natural forage and inadequate diet, habitat

30. *See* Tan & Epley, *supra* note 9, at 304.

31. MARTHA GROOM ET AL., PRINCIPLES OF CONSERVATION BIOLOGY 86 (Sinauer Associates, Inc. 3rd ed. 2005).

32. *Id.*

33. OFFICE OF THE PRESS SEC'Y, *Fact Sheet: The Economic Challenge Posed by Declining Pollinator Populations*, THE WHITE HOUSE 1, 1 (June 20, 2014), http://www.fs.fed.us/wildflowers/pollinators/documents/PresMemoJune2014/PollinatorFactSheet-PresMemo.pdf.

34. *Id.*; U.S. DEP'T OF AGRIC., *Pollinators: Our Future Flies on the Wings of Pollinators*, http://www.fs.fed.us/wildflowers/pollinators/index.shtml (last visited Sept. 17, 2015).

35. GROOM ET AL., *supra* note 31, at 54.

loss, modification, and fragmentation, agricultural and grazing practices, pesticide use, loss of genetic diversity, agricultural practices and pesticides and herbicides.[36]

Pollinators include a diverse array of organisms, primarily ants, bats, bees, beetles, birds, butterflies, flies, moths, and wasps.[37] Many of these pollinators are endangered or threatened, but declines in insect species often get overlooked due to their small size and culturally abhorrent reputation.[38] The *Red List of Pollinator Insects of North America* names dozens of butterflies and bees that are facing significant threats of endangerment, and the world is seeing increased population declines in native pollinators, such as bumble bees, as well as migrating species, such as Monarch Butterflies.[39] Pollinators federally listed as endangered or threatened include the Bay Checkerspot butterfly, the Dehli Sands Flower-loving fly, and the Valley Elderberry Longhorn Beetle.[40] Over 30 species of bees are critically imperiled and possibly extinct, including Franklin's bumble bee and several yellow-faced bees.[41] While the FWS has not formally listed any bee-species as endangered, it nonetheless recognizes the need to. For instance, in 2011, the Pacific Islands Office of the Fish and Wildlife Service found that seven species of yellow-faced Hawaiian bees warranted listing as an endangered species and the Oregon Fish and Wildlife Office found that the Franklin's bumble bee also warranted listing as an endangered species.[42] The FWS is still

36. Fish and Wildlife Service, *Pollinators in Decline – Causes* http://www.esa.org/ecoservices/poll/body.poll.scie.decl.html (last visited Oct. 14, 2014); Office of the Press Secretary, *Fact Sheet: The Economic Challenge Posed by Declining Pollinator Populations*, THE WHITE HOUSE 1, 1 (June 20, 2014), http://www.fs.fed.us/wildflowers/pollinators/documents/PresMemoJune2014/PollinatorFactSheet-PresMemo.pdf.

37. United States Department of Agriculture, *Our Future Flies on the Wings of Pollinators* http://www.fs.fed.us/wildflowers/pollinators/index.shtml (last visited Oct. 14, 2014).

38. Fish and Wildlife Service, *Pollinators in Decline – Causes* http://www.esa.org/ecoservices/poll/body.poll.scie.decl.html (last visited Oct. 14, 2014).

39. *See* United States Fish and Wildlife Service, *Pollinators: Endangered Species Program* http://www.fws.gov/pollinators/Programs/Endangered.html (last visited Oct. 14, 2014) (lists endangered and threatened pollinators); Office of the Press Secretary, *Fact Sheet: The Economic Challenge Posed by Declining Pollinator Populations*, THE WHITE HOUSE 1, 1 (June 20, 2014), http://www.fs.fed.us/wildflowers/pollinators/documents/Pres Memo June2014/PollinatorFactSheet-PresMemo.pdf.

40. *Pollinators: Endangered Species Program*, *supra* note 39.

41. The Xerces Society for Invertebrate Conservation, *Red List of Bees: Native Bees in Decline* http://www.xerces.org/pollinator-redlist/# (last visited Feb. 11, 2015).

42. Pacific Islands Fish and Wildlife Office, *News Release: Endangered Species Listing Warranted for 7 Species of Hawaiian Yellow-faced Bees*, UNITED STATES FISH

considering these bee species for listing. The National Resources Defense Council and Xerces Society sued the FWS to list the rusty patched bumble bee in 2014, and the suit is pending.[43] Hundreds of vertebrate pollinator species are also on the verge of extinction (at least fifteen are endangered).[44] Scientists are already seeing cascade effects (i.e., one species extinction causing secondary extinctions in other dependent species) resulting from pollinator-endangerment and presume these effects will be devastating and irreparable if they persist.[45] President Obama's recent directive "Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators" requires numerous agencies to prioritize the conservation of pollinators.[46] The agricultural industry, GE industry, and the world, cannot underestimate the importance of pollination as an ecosystem service and the implications of its decline. Though the agricultural industry has felt the economic impacts resulting from a decline in pollination services, GMOs, which threaten the survival of pollinating species, have gained popularity.

IV. Adverse Effects of GMOs: The Scientific Evidence of GMO Impact on Pollinators

While some in the scientific community dispute that GMOs have a direct adverse impact on species, studies prove that GMOs have indirect adverse effects on biodiversity.[47] Biodiversity, i.e., biological

AND WILDLIFE SERVICE 1, 2 (Sep. 6, 2011), http://www.fws.gov/pacificislands/news%20releases/Final%20News%20Release%20%2012%20month%20HI%20Yellow-faced%20bees%20090611.pdf.

43. Mica Rosenberg, *Environmentalists sue to list bumble bee as endangered*, REUTERS (May 13, 2014), http://www.reuters.com/article/2014/05/13/us-usa-environment-bees-idUSKBN0DT21F20140513.

44. Fish and Wildlife Service, *Pollinators in Decline—Causes* http://www.esa.org/ecoservices/poll/body.poll.scie.decl.html (last visited Oct. 14, 2014).

45. *Id.*

46. Office of the Press Secretary, *Presidential Memorandum—Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators*, THE WHITE HOUSE (June 20, 2014), http://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b.

47. *See* Dirk S. Schmeller & Klaus Henle, *Cultivation of genetically modified organisms: resource needs for monitoring adverse effects on biodiversity*, 17 BIODIVERSITY & CONSERVATION 3551, 3553 (2008) (showing negative impacts of GMOs on habitat, feeding, and predator-prey dynamics of keystone and at-risk i.e., endangered or threatened or vulnerable species); Lora A. Morandin, *Genetically Modified Crops: Effects on Bees and Pollination*, *in* BEE POLLINATION IN AGRICULTURAL ECOSYSTEMS 203, 207, 213 (R. James & T. Pitts-Singer eds., 2008) (direct lethal impacts on bees are difficult to assess since there are thousands of species of bees and various potential genetic mutations

diversity, "refers to the variety of living organisms, their genetic diversity, the diversity of evolutionary lineages, and the types of ecological communities into which they are assembled."[48] Less-understood, sublethal effects could negatively impact bees more than better-understood, lethal effects.[49] Different gene expression might lead to altered levels of nectar or floral appearance, both essential attributes for attracting pollinators.[50] The negative effects from GM pollen could potentially implicate the mortality of other pollinators, many species of which are listed for protection under the ESA.[51]

Increasingly, scientific research is unveiling the direct negative impacts of transgenic crops on nontarget organisms and the cascading effect that has on species necessary for pest control and maintenance of ecological foodwebs. Studies on herbicide tolerant GM crops, for example, show a decrease in nontarget arthropod biodiversity due to a decrease in weedy habitat as a result of glyphosate application (an herbicide).[52] A decrease in weedy habitat also decreases seedling abundance, which negatively impacts bird survival because birds depend on seedlings for food.[53] Weedy abundance can impact native

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of GE pollen post-environmental release); P. Han, *Quantification of toxins in a Cry1Ac + CpTI cotton cultivar and its potential effects on the honey bee Apis mellifera L.*, 19 ECOTOXICOLOGY 1452, 1457 (2010), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2995320/ (showing the anti-feedant effects of GMOs on bees, disrupting feeding and foraging patterns); Gunther Latsch, *Collapsing Colonies: Are GM Crops Killing Bees?*, SPIEGEL ONLINE (Mar. 22, 2007), http://www.spiegel.de/international/world/collapsing-colonies-are-gm-crops-killing-bees-a-473166.html (showing sublethal impacts effects on bees make bees more susceptible to pathogens and disease); Matthias Schindler et al., *Monitoring agricultural ecosystems by using wild bees as environmental indicators*, 8 BIORISK 53, 59 (2013), available at http://biorisk.pensoft.net/articles.php?id=1899. (showing anti-feedant effects result in a negative impact on viability of wild bee populations); Morandin & Winston, *supra* note 18, at 876–77 (showing lower abundances of wild bee populations and pollination deficits are found together in GM agricultural plots compared to conventional and organic plots).

48. GROOM ET AL., *supra* note 31, at 60.

49. *Id.* at 206.

50. *Id.* at 210.

51. *Pollinators: Endangered Species Program*, *supra* note 39.

52. Osamu Imura et al., *Assessing the effects of cultivating genetically modified glyphosate-tolerant varieties of soy beans (Glycine max (L.) Merr.) on populations of field arthropods*, 9 ENVIRON. BIOSAFETY RES. 101, 108 (2010), http://www.ncbi.nlm.nih.gov/pubmed/21288465; AJ Haughton et al., *Invertebrate responses to the management of genetically modified herbicide-tolerant and conventional spring crops. II. Within-field epigeal and aerial arthropods*, 358 PHILOS. TRANS. R. SOC. LOND. B. BIO. SCI. 1863, 1872–73, 1875 (2003), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1693277/.

53. A.R. Watkinson et al., *Predictions of Biodiversity Response to Genetically Modified Herbicide-Tolerant Crops*, 289 SCIENCE 1554, 1556 (2000), http://nctc.fws.gov/

bee populations, which tend to be greater in areas with greater plant diversity and abundance.[54] Despite these impacts, the only Supreme Court opinion resulting from a line of cases addressing GMO impacts on endangered species turned on the procedural requirements of an injunction on GMOs, rather than the merits of GMO regulation based on threats to endangered species.

V. Judicial Interpretation of GMO Regulation Under the ESA

The battle over Roundup Ready Alfalfa ("RRA") deregulation remains the most pertinent legal controversy regarding judicial review of GMOs and their impact on ecosystems. The seminal case addressing RRA deregulation was the Supreme Court decision *Monsanto Co. v. Geertson Seed Farms*.[55] In 2005, the USDA, specifically the Animal and Plant Health Inspection Service ("APHIS"), granted Monsanto's petition to deregulate RRA, a genetically engineered variety of alfalfa resistant to Monsanto's Roundup herbicide (i.e., glyphosate).[56] In so doing, APHIS warned Monsanto in its Notice of approval that RRA "should not reduce the ability to control pests and weeds in alfalfa or other crops."[57] APHIS issued a similar Notice in deregulating GE sugar beets.[58] Deregulation of a GMO is an agency action that may adversely affect the environment, and therefore, APHIS must follow the information-forcing procedure, established by the National Environmental Policy Act ("NEPA"), in issuing deregulation.

NEPA requires federal agencies, such as APHIS, to prepare a detailed EIS for all "major Federal actions significantly affecting the quality of the human environment."[59] NEPA ensures that an agency will carefully consider impacts on the environment and will make

resources/course-resources/pesticides/GMOs/predictions-of-bidiversity-response-to-gmo-watkinson-et-al-2000.pdf.

54. *Supra* note 138, at 210–11.

55. Mosanto Co. v. Geerston Seed Farms, 561 U.S. 139, 141 (2010).

56. Animal and Plant Health Inspection Servs., *Roundup Ready Alfalfa History*, U.S. DEP'T OF AGRIC. (Dec. 16, 2014), http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology/sa_news/ct_alfalfa_history/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzd3V2dDDz93HwCzL29jAyMTPULsh0VAU1Vels!/.

57. Monsanto Co. and Forage Genetics International; Availability Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate, 70 Fed. Reg. 36,917, 36,918-19 (June 27, 2005).

58. Monsanto Co. and KWS SAAT AG; Determination of Nonregulated Status for Sugar Beet Genetically Engineered for Tolerance to the Herbicide Glyphosate, 70 Fed. Reg.13,007, 13,008 (Mar. 17, 2005).

59. 42 USC § 4332(2)(C).

relevant information available to the public.[60] The "threshold question in a NEPA case is whether a proposed project will 'significantly affect' the environment, thereby triggering the requirement for an EIS."[61] The agency must conduct an Environmental Assessment to determine if an action may cause a significant impact. If no significant impact is found, it must issue a statement explaining its Finding Of No Significant Impact; if a significant impact is found, the agency must conduct an EIS.[62]

The litigation battle in *Geertson Seed Farms* began with APHIS's deregulation of RRA. In its 2005 Environmental Assessment, APHIS found that RRA did not pose a significant plant-pest risk and it was, therefore, "no longer considered regulated articles under 7 CFR part 340."[63] APHIS's Finding Of No Significant Impact in 2005 noted that once deregulated, RRA would not be subject to "isolation distances," i.e., regulations would not require farmers to grow RRA more than two miles away from conventional and organic alfalfa crops.[64] APHIS concluded that the risk of gene transmission was insignificant because the organic farmer is responsible for ensuring their crops avoid cross-pollination from neighboring operations.[65] In response to concerns about weed resistance, APHIS stated that while RRA could lead to glyphosate-resistant weeds, farmers could use other effective herbicides on the market for weed eradication, and therefore, weed-resistance was not a significant impact necessitating an EIS.

Organic and conventional farmers challenged the APHIS decision to deregulate RRA.[66] Plaintiffs asserted that there was a risk of genetic contamination, i.e., pollen-drift.[67] Neither of the parties disputed the fact that insect pollination for alfalfa can occur at least two miles from the pollen source.[68] The district court determined that

60. *See id.*

61. Geertson Seed Farms v. Johanns, No. C 06-01075 (CRB), 2007 WL 518624, at *3 (N.D. Cal. Feb. 13, 2007).

62. *Id.* at *4.

63. Animal and Plant Inspection Services, *Glyphosate-Tolerant Alfalfa Events J101 and J163: Request for Nonregulated Status*, UNITED STATES DEPARTMENT OF AGRICULTURE i, ii (Dec. 2010), http://blogs.desmoinesregister.com/dmr/wp-content/uploads/2010/12/AlfalfaEIS.pdf (final EIS); *Johanns*, 2007 WL 518624, at *3.

64. *Johanns*, 2007 WL 518624, at *2.

65. *Id.*

66. *Id.* at *1.

67. *Id.* at *2.

68. *Id.*

due to bee pollination and the high geographic concentration of alfalfa seed production, there is a realistic potential for gene transmission to non-genetically engineered crops.[69] Once contaminated, farmers are unable to eradicate or control the spread of the Roundup Ready gene. Since alfalfa is a perennial crop, the crop is only planted every 3-4 years.[70] APHIS's Finding of No Significant Impact determination relied solely on the conclusion that organic and conventional farmers hold the responsibility to prevent gene transmission—regardless of whether the farmers can actually protect their crops from contamination.[71]

Regarding Plaintiff's second contention that weed resistance results from increased use of Roundup on crops, the court found APHIS's response "cavalier": The mere existence of other methods to eradicate weeds is irrelevant if farmers do not use those methods.[72] The court also determined that APHIS failed to evaluate the cumulative impact of planting Roundup Ready crop varietals and increased use of glyphosate.[73] Thus, APHIS "did not take the 'hard look' NEPA requires."[74] The district court enjoined use of RRAs until APHIS conducted an EIS.[75] The court dismissed claims brought under the ESA and PPA as premature because APHIS had to produce an EIS before the court could adjudicate those claims.[76]

The Ninth Circuit affirmed the district court ruling; but the Supreme Court reversed, concluding that the district court abused its discretion in issuing a nationwide permanent injunction on RRA pending the completion of an EIS.[77] The Supreme Court rejected Monsanto's standing argument, reasoning that the Plaintiffs would suffer sufficiently concrete harms to satisfy the injury-in-fact prong of the constitutional standing requirement.[78]

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69. *Id.* at *5.

70. *Id.*

71. *Id.* at *6.

72. *Id.* at *6, *10.

73. *Id.* at *9–10.

74. *Id.* at *10.

75. *Id.*

76. *Id.* at *12.

77. Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 141 (2010).

78. *Id.* at 155–57. The Court reiterated that in order to grant a permanent injunction the plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and

The Court, however, ruled that the district court's findings did not meet the requirements for a permanent injunction because the district court did not consider that APHIS had the option to partially deregulate RRA pending EIS completion.[79] In his dissent, Justice Stevens asserted that the "Court ignore[d] the district court's findings that gene flow is likely and that APHIS has little ability to monitor any conditions imposed on a partial deregulation."[80] Therefore, Justice Stevens noted "the [district] court may have felt it especially prudent to wait for an EIS before concluding that APHIS could manage RRA's threat to the environment" and "the district court was well within its discretion to order the remedy that the Court now reverses."[81]

In 2011, APHIS completely deregulated RRA stating that because it had not identified any plant pest risks associated with RRA, APHIS did not have existing statutory authority to regulate RRAs under a partial deregulation alternative (such as mandating isolation distances and geographic restrictions to reduce risk of transgenic contamination).[82] However, "APHIS acknowledged that full deregulation could lead to transgenic contamination through the transfer of pollen or seed mixing, increased use of glyphosate, and the evolution and proliferation of glyphosate-resistant weeds" and the "no action alternative as the 'environmentally preferred alternative.'"[83]

In response to the deregulation, plaintiffs filed various claims against the defendants under the Plant Protection Act, ESA, and NEPA. The district court found that Congress did not intend for "APHIS to regulate commercial crops as plant pests because they pose a risk of transgenic contamination" in the Plant Protection Act. The Plant Protection Act does not require APHIS "to consider the effects of increased herbicide use or the development of herbicide resistant weeds in making this assessment."[84] Ultimately, the court held that APHIS's interpretation of the Plant Protection Act was entitled to deference; namely, that there was no plant pest risk, and

defendant, a remedy in equity is warranted and (4) that the public interest would not be disserved by a permanent injunction.

79. *Id.* at 160.

80. *Id.* at 182 (Stevens, J., dissenting).

81. *Id.* at 184, 185.

82. Ctr. for Food Safety v. Vilsack, 844 F. Supp. 2d 1006, 1011 (N.D. Cal. 2012).

83. *Id.*

84. *Id.* at 1015, 1016.

therefore APHIS did not have regulatory authority to continue to manage RRAs under a partial deregulation scheme.[85] Therefore, the court dismissed Plaintiffs' NEPA claims, reasoning that APHIS took a "hard look" at alternatives and mitigation measures, and that was all that was required of the agency under NEPA.[86]

In so doing, the district court stated, "Plaintiffs' ESA claim ultimately turns on whether APHIS's actions are the legally relevant cause of increased glyphosate use."[87] The district court stated that "where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect" and that a "'but for' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA."[88] The district court held that "APHIS is not the legally relevant cause of the glyphosate use complained of by Plaintiffs" since APHIS found no plant pest risk, and APHIS only has jurisdiction when a plant pest risk exists.[89] Because APHIS lacked "discretionary authority to regulate the crop" it "could not be obligated to conduct additional ESA analysis." The court further determined that Congress delegated that authority to the EPA through Federal Insecticide, Fungicide, and Rodenticide Act.[90] The court also expressed concerns about the EPA's exercise of this power: "If Plaintiffs allegations are true, then it is disturbing that EPA has yet to assess the effects of glyphosate on most of the species found near the acreage on which RRA will be planted and glyphosate will be used."[91] Even though the EPA would not conduct a complete, national EIS regarding RRA glyphosate use until 2015, the court did not discuss this factor because EPA was not a party to the case.[92] The saga of alfalfa deregulation continued on appeal in the Ninth Circuit. The Court of Appeals upheld the district court opinion, explaining:

> The ESA's requirements would come into play only when an action results from an exercise of agency discretion. . . .

85. *Id.* at 1018.
86. *See id.* at 1022.
87. *Id.* at 1019.
88. *Id.* at 1019–20.
89. *Id.* at 1020.
90. *Id.*
91. *Id.*
92. *Id.* at 1020–21.

> . . . .
>
> Here, once APHIS concluded that RRA was not a plant pest because it did not cause plant pest injury to plants, the agency had no jurisdiction to continue regulating the crop. The agency's deregulation of RRA was thus a nondiscretionary act that did not trigger the agency's duty to consult under the ESA.[93]

Thus, at the moment, no federal agency is truly evaluating and considering the impacts of GMOs on endangered or threatened species and on the ecosystems upon which organisms depend.

Geertson Seed Farms is the only GMO lawsuit heard before the Supreme Court whose legal claim derived, in part, from GMO biodiversity impacts. The Supreme Court's ruling, however, only addressed the district court's abuse of discretion in granting injunctive relief; the Court did not rule on the merits of the ESA claim.[94] On remand, the lower court held that the USDA did not have jurisdiction over glyphosate use (the EPA has jurisdiction), and, therefore, APHIS does not have to consider such cumulative impacts in its Environmental Assessments.[95] The problem is that the EPA does not have jurisdiction over plants—it only has jurisdiction over the herbicidal and pesticidal compounds in the plant.[96] The impact of the district court's decision is that the EPA does not have to take into account where and how many GMOs are planted in its Environmental Assessments of herbicides because the EPA does not have regulatory authority. Therefore, Environmental Assessments conducted by both the USDA and the EPA are inherently flawed because they do not take into account the cumulative impact of herbicide-resistant GMO abundance with coinciding increases of herbicide use. The best way to address this regulatory loophole is to enforce a § 7 consultation with the FWS whereby the agency must consider the adverse effect of such cumulative impacts on pollinators and the continued survival of species essential to functioning agroecosystems.

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93. Ctr. for Food Safety v. Vilsack, 718 F.3d 829, 842 (9th Cir. 2013) (citations omitted).

94. Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 141 (2010).

95. *Vilsack*, 844 F. Supp. 2d at 1011.

96. 7 U.S.C. §§ 136a(c)(5)(C)-(c)(5)(D); *see also* Rebecca M. Bratspies, *Is Anyone Regulating? The Curious State of GMO Governance in the United States*, 37 VT. L. REV. 923, 937 (2013).

VI. The ESA § 7 Consultation Mandate and Deregulation of GMOs: Preemption Under The Supremacy Clause

The first general recommendation in the Coordinate Framework directive states that "[h]armonization of approaches to rDNA technology can be facilitated by exchanging: principles or guidelines for national regulations; developments in risk analysis; and practical experience in risk management. Therefore, information should be shared as freely as possible."[97] The legislation underlying the Coordinated Framework endorses the free flow of information, transparency, and effective risk management. The legislative intent to prioritize mitigation of risk by maintaining open lines of communication between agencies supports mandatory § 7 consultations in light of adverse impacts on biodiversity.

The stated purpose of the ESA is "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved."[98] Interpreting the statutory mandate to protect biodiversity, the Court in *Tennessee Valley Authority v. Hill* held that the value of species is incalculable, and as such, Congress intended to preserve species and grant endangered species the highest protection when it passed the ESA.[99] The ESA requires the FWS to make decisions based on the "best available science and commercial data" rather than relying on the inconclusiveness of data to make "mere conclusions."[100] Section 7 of the ESA requires the government to consult with the FWS *before* taking any action that affects a protected species.[101] The Secretary must make listing decisions "solely on the basis of the best scientific and commercial data available to him."[102] This standard suggests that the ESA requires the U.S. government to take precaution and have sufficient data before taking an action that would impact an endangered or threatened species.[103] Due to GMO's adverse effects on biodiversity, under the ESA, the FWS has regulatory jurisdiction over an agency's decision to deregulate any GMO.

97. Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50856, 50857 (proposed Dec. 31, 1984); Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (1986).

98. 16 U.S.C. § 1531(b).

99. Tennessee Valley Authority v. Hill, 437 U.S. 153, 178 (1978).

100. N. Spotted Owl v. Lujan, 758 F. Supp. 621, 628 (W.D. Wash. 1991).

101. *See* 16 U.S.C. § 1536.

102. 16 USC §1533(b)(1)(A).

103. See 16 U.S.C. § 1536 for consultations regarding government action.

The House Report accompanying the ESA explains Congress's intent to preserve genetic diversity:

> From all the evidence available to us, it appears that the pace of disappearance of species is accelerating. As we homogenize the habitats in which these plants and animals evolved, and as we increase the pressure for products that they are in a position to supply (usually unwillingly) we threaten their—and our own—genetic heritage.
>
> The value of this genetic heritage is, quite literally, incalculable.... If the blue whale, the largest animal in the history of this world, were to disappear, it would not be possible to replace it—it would simply be gone. Irretrievably. Forever.
>
> ....
>
> From the most narrow possible point of view, it is in the best interests of mankind to minimize the losses of genetic variations. The reason is simple: they are potential resources. They are keys to puzzles which we cannot solve, and may provide answers to questions which we have not yet learned to ask.
>
> ....
>
> Man can threaten the existence of species of plants and animals in any of a number of ways, by excessive use, by unrestricted trade, by pollution or by other destruction of their habitat or range. The most significant of those has proven to also be the most difficult to control: the destruction of critical habitat.[104]

Congress intended the ESA to protect against precisely the kinds of harms resulting from GMO deregulation: the habitat destruction of pollinators by way of genetic contamination, increased use of chemical treatments, and disruption of feeding. If the current regulatory framework cannot enforce mandatory § 7 consultations, then the Coordinated Framework structure should be amended to include the FWS.

The federal regulatory system includes both an approach of pristine-preservation and restoration, as well as a resource-based,

104. H.R. REP. NO. 93-412, at 143–44 (1973).

utilitarian approach to environmental protection, making such regulation a difficult task.[105] For example, the U.S. Forest Service maintains and protects our forests, but also governs timber extraction.[106] The National Marine Fisheries Service conserves marine resources, but must also provide for commercial fisheries.[107] The National Park Service has to preserve the natural and pristine park environment, but also has to allow for human recreational activity.[108] To deal with these dichotomous obligations, the government has to take an integrative approach to ecosystem management and sustainability of resources. Former Director of the U.S. Fish and Wildlife Service, Jamie Rappaport Clark, noted:

> Decisions to list a species as threatened or endangered take into account not only population size, but also the degree of threat, based on factors like disease, habitat loss, and commercial use. We need to understand all these factors if we are to make smart choices about how to best conserve species and their habitats.[109]

The FWS is no exception; this agency is responsible for analyzing and responding to biodiversity threats, while taking into account potentially conflicting commercial uses of resources. GMOs implicate a wide variety of issues including resources, food security, intellectual property, human health, and biodiversity. The FWS certainly has a role to play in its regulation, whether through a § 7 consultation or legislative amendment, such that the Coordinated Framework includes the FWS.

Regulating the introduction of GMOs under the ESA should remain solely under the purview of federal regulatory power. The Supremacy Clause states that the Constitution and laws and treaties made pursuant to it are the supreme law of the land, and that federal law controls and invalidates state law if conflict arises between state and federal law.[110] Section 1535(f) of the ESA expressly preempts state laws that are less restrictive than the ESA: "Any State law or regulation respecting the taking of an endangered species or

105. GROOM ET AL., *supra* note 31, at 13.
106. *Id.*
107. *Id.*
108. *Id.*
109. *Id.*
110. U.S. CONST. art. VI.

threatened species may be more restrictive than the exemptions or permits provided for in this [Act] or in any regulation which implements this [Act] but not less restrictive than the prohibitions so defined."[111] Therefore, Congress expressly established a threshold level of federal biodiversity protection by passing the ESA.

GMO introductions into the environment endanger pollinators and as such could likely be considered a "regulation respecting the taking of an endangered or threatened species." So strong is the causal link between GMO introductions and ecosystem disruption that any state law allowing such regulations without FWS consultations falls short of the protection level established by Congress in the ESA. Under the ESA, GMO introductions constitute a taking of endangered pollinators, and in accordance with its powers under the Supremacy Clause, Congress has expressly established that the ESA provides the baseline level of endangered or threatened species protection. Therefore, states cannot regulate the introduction of GMOs into our environment as long as those regulations are so permissive that they violate the conservation measures of the ESA.

VII. ESA Regulation of GMO Introductions Under the Commerce Clause and the Necessary and Proper Clause

Under its constitutionally enumerated powers, the federal government has the authority "to regulate commerce with foreign nations, and among the several states, and with the Indian tribes."[112] Commerce includes all stages of business and Congress can regulate any activity, including intrastate activity that has a substantial effect on interstate commerce and persons or things in interstate commerce.[113] Congress can regulate activities that individually have little effect, but cumulatively have a substantial effect on interstate commerce.[114] The Court defers to congressional assessments of an activity's effect on interstate commerce as long as a rational basis exists for doing so.[115] Notably, the Court in *United States v. Lopez* concluded that the "substantial effect" on interstate commerce can be measured by aggregating the effects of individual activities, but only if

111. National Audubon Society v. Davis, 307 F.3d 835 (9th Cir. 2002) (holding that the California ban on the use of leghold traps was preempted by the ESA).

112. U.S. CONST. art. I, § 8, cl. 3.

113. Wickard v. Filburn, 317 U.S. 111, 124 (1942); United States v. Lopez, 514 U.S. 549 (1995).

114. *Lopez*, 514 U.S. at 549; *Wickard*, 317 U.S. at 127–28.

115. Katzenbach v. McClung, 379 U.S. 294, 304 (1964).

those individual activities are themselves "economic" or "commercial" in nature.[116] In *Gonzales v. Raich*, the Court defined an economic activity as an activity having to do with "production, distribution, and consumption of commodities."[117] There, the Court held that Congress can regulate intrastate, noncommercial activities when doing so is necessary to the success of a broader, interstate regulatory scheme.[118]

Under the Necessary and Proper Clause, a regulation is permissible when it is an "essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated."[119] Thus, determining whether the commerce clause doctrine justifies congressional regulation of an activity turns on whether the activity is economic: If the activity is economic, Congress may aggregate the individual effects of an activity to determine whether the overall impact results in a substantial effect on interstate commerce (i.e., rational basis); if the activity is noneconomic, Congress's findings on the effects of the activity on interstate commerce receive deference if the activity is part of a larger regulatory scheme.[120]

In 2011, the Ninth Circuit upheld § 7 consultation requirements of the ESA against a Commerce Clause challenge. In *San Luis & Delta-Mendota Water Authority v. Salazar*, almond, pistachio, and walnut farmers sued FWS for violating the Commerce Clause by preventing completion of state water projects on behalf of endangered delta smelt protection.[121] In its biological opinion, the FWS found that state water projects constituted a taking of endangered delta smelt because such projects threatened the continued existence of the species.[122] Plaintiff-farmers claimed that enforcing ESA consultation requirements for (as well as subsequent protection of) delta smelt was unconstitutional because the delta

116. *Lopez*, 514 U.S. at 555–56; *Wickard*, 317 U.S. at 125.

117. Gonzales v. Raich, 545 U.S. 1, 25 (2005).

118. *Id.* at 22.

119. *Id.* at 24–25.

120. *Id.*; *Lopez*, 514 U.S. at 557.

121. San Luis v. Salazar, 638 F. 3d 1163, 1168 (9th Cir. 2011).

122. *Id.* at 1167. The FWS issues a biological opinion following a consultation. The biological opinion is a statement explaining how the government's proposed action will affect an endangered or threatened species and suggests "reasonable and prudent alternatives" to the agency action (if any exist) that will not violate the ESA. 16 U.S.C. § 1536(b)(3)(A). *See also Conultations: Frequently Asked Questions*, U.S. FISH AND WILDLIFE SERVICE, http://www.fws.gov/endangered/what-we-do/faq.html.

smelt is purely an intrastate species with no commercial value; therefore, applying this requirement to the operation of California's water distribution system was "an invalid exercise of constitutional authority [under the Commerce Clause]."[123] The court held that the Commerce Clause challenge to § 7 of the ESA failed because species protection "bears a substantial relation to commerce."[124]

The court articulated several reasons why protecting threatened or endangered species is an economic activity: Endangerment may be a direct result of overexploitation of the species for commercial purposes; the ESA serves to prevent interstate commerce of protected species; the "ESA protects the future and unanticipated interstate-commerce value of species," and recovery of an endangered or threatened species may lead to a market for commercial use of those species.[125] Particularly relevant to this note, the court stated that "[t]he genetic diversity provided by endangered or threatened species improves agriculture and aquaculture, which clearly affect interstate commerce."[126] The court explained that the only requirement to pass muster under the Commerce Clause "is that 'the comprehensive regulatory scheme' have a 'substantial relation to commerce'" and does not need to be a "purely economic or commercial statute."[127]

In a more recent case in Utah, the district court struck down protection of the threatened Utah prairie dog because protection of a purely intrastate species was not an economic activity that substantially affected interstate commerce.[128] The court held that "[a]lthough the Commerce Clause authorizes Congress to do many things, it does not authorize Congress to regulate takings of a purely intrastate species that has no substantial effect on interstate commerce."[129] The court specified that the substantial effect test is concerned with the "regulated activity": "The question in the present case is whether take of the Utah prairie dog has a substantial effect on interstate commerce, not whether the regulation preventing the take has such an effect" and the Commerce Clause was not meant to

123. *San Luis*, 638 F. 3d at 1168.

124. *Id.* at 1174.

125. *Id.* at 1176.

126. *Id.*

127. *Id.* at 1177.

128. People for the Ethical Treatment of Prop. Owners v. U.S. Fish & Wildlife Serv., 57 F. Supp. 3d 1337 (D. Utah 2014).

129. *Id.* at 1346.

regulate ecosystems.[130] The court found that the prairie dog itself had no substantial effect on interstate commerce and that the causal link of prairie dog extinction and other species extinction was too attenuated.[131] The court concluded that protection of the prairie dog was not necessary to the ESA's economic scheme because "takes of Utah prairie dogs on non-federal land—even to the point of extinction—would not substantially affect the national market for any commodity regulated by the ESA."[132] Reasoning that Congress did not have authority under the Commerce Clause or Necessary and Proper Clause, the district court held that Congress did not have authority to regulate takings of prairie dogs on non-federal land.[133]

Unlike the attenuated effects of prairie dog extinction, the substantial effect of pollinator endangerment on the entire agricultural industry is unquestioned. Farmers have already experienced severe declines in agricultural productivity due to the growing disappearance of pollinators. The scientific community is largely in agreement that loss of habitat and loss of natural forage negatively impact bee population abundance and species distribution. As discussed earlier, many studies and basic principles of biology indicate that introduction of GMOs into the environment and concomitant agricultural practices decrease habitat and forage upon which various endangered and threatened species of bees depend.

These adverse effects of GMOs on pollinator biodiversity substantially affect agriculture, an economic activity, by putting almost seventy-five percent of our crops at risk (as pollinators are responsible for the growth of nearly seventy-five percent of our crops).[134] The federal government has the power to regulate the growth of GMOs under the Commerce Clause and should do so under the Necessary and Proper Clause as protecting endangered pollinators is necessary for the overall regulatory scheme of the ESA (i.e., protecting endangered species). The ESA regulatory scheme "has a substantial relation to commerce" since protecting pollination dynamics is necessary for the nation's commercial agricultural industry. Thus, the constitutionally enumerated powers granted to

130. *Id.* at 1344.

131. *Id.* at 1344–45.

132. *Id.* at 1346.

133. *Id.* at 1345–46.

134. *Pollinators*, U.S. FISH AND WILDLIFE SERVICE, http://www.fws.gov/ pollinators/ Index.html (last visited Oct. 4, 2015).

Congress justify and necessitate more demanding restrictions on the use of GMOs.

Conclusion

Scientific studies show that GMOs have an adverse impact on biodiversity. Despite the GMO industry defense that GMOs benefit the environment by reducing the need for pesticides and herbicides, studies show that the use of these and other toxic chemicals has actually increased with the introduction of GMOs into our agricultural system.[135] Pest and weed resistance results from these GMO industry practices, and this threatens food resources and habitat for pollinators. When a government action threatens the survival of a species, the government must consult with the FWS before carrying out the action. Deregulating GMOs threatens the survival of pollinators; therefore, the EPA and USDA must consult with the FWS before approving GMO deregulations.

135. Benbrook, *supra* note 17.